

## **DETAILED ACTION**

The receipt is acknowledged of applicants' amendment filed 04/20/2011.

Claims 1, 3-7, 9-19, 21-23 are pending and included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3-7, 9-11, 18, 19, 22, 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 22 are amended to recite that "the therapeutic agent is non-salt agent". Recourse to the

specification, no support has been found for such a limitation. To the contrary, paragraph 0053 of the published application recites “pharmaceutically acceptable salts, esters, solvates and clathrates thereof.” If applicant contends there is support for this limitation, then applicant is requested to specify the page and line of said support. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

The test for determining compliance with the written description requirement is whether the disclosure of the application as **originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language.** See *In re Kaslow*, 707 F 2d 1366, 1375 (Fed. Cir. 1983). See MPEP 2163.06.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. **The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.** See *Genetech*, 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1, 4-7, 9-19, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa (JP 61-126020, IDS filed 03/27/2009) in view of Miranda et al. (US 5,474,783, of record).

### **Applicant Claims**

Currently amended claim 1 is directed to a non-reactive pressure sensitive adhesive composition comprising an acrylic polymer and a therapeutic agent, wherein the acrylic polymer

(i) is prepared from monomers selected from the group consisting of alkyl acrylate monomers, alkyl methacrylate monomers, polymerizable non-cyclic nitrogen-containing monomers and mixtures thereof,

wherein said alkyl acrylate monomers and alkyl methacrylate monomers have up to about 18 carbon atoms in the alkyl group, and

wherein said polymerizable non-cyclic nitrogen-containing monomers are selected from the group consisting of t-octyl acrylamide, dimethyl acrylamide, t-butyl acrylamide, i-propyl acrylamide, N-phenyl acrylamide, vinylacetamides, nitriles, and mixtures thereof,

and

wherein said alkyl acrylate monomers and/or alkyl methacrylate monomers are present in the acrylic polymer in amounts of from about 50 to about 98%, based on a dry weight basis of the total monomer weight of the acrylic polymer, and said polymerizable non-cyclic nitrogen-containing monomers are present in the acrylic

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polymer in amounts of from about 2 to about 50%, based on a dry weight basis of the total monomer weight of the acrylic polymer,

- (ii) lacks functional groups containing reactive hydrogen moieties and
  - (iii) contains no post-polymerization chemical crosslinking,
- and wherein the therapeutic agent is a non-salt agent.

Currently amended claim 12 recites a transdermal drug delivery device comprising a layer of the non-reactive pressure sensitive adhesive as set forth and backing layer, wherein the therapeutic agent is fentanyl.

Currently amended claim 22 recites a transdermal drug delivery device comprising the non-reactive pressure sensitive adhesive as set forth, wherein the therapeutic agent is a non-salt agent.

#### **Determination of the Scope and Content of the Prior Art**

##### **(MPEP §2141.01)**

Nakagawa teaches patch for external use comprising active agent in an acrylic adhesive layer. The acrylic adhesive is a copolymer of (meth)acrylic acid alkyl ester and a monomer having an amide bond including butyl acrylamide and dimethyl acrylamide (page 118, right column). Example 1, page 120 of the reference, discloses copolymer composition composed of 30% 2-ethylhexyl methacrylate, 61% butyl acrylate which form 91% of alkyl acrylate monomer, and 9% functional acrylamide. The amounts of the monomers as disclosed by the reference falls within the claimed ranges, therefore the reference anticipates the claims. The reference disclosed (meth)acrylic acid alkyl ester

having 1-8 carbon atoms. Monomers having an amide bond further include octyl-acrylamide, dimethyl acrylamide, and butyl acrylamide. See page 118, right column. The acrylic polymer disclosed by the reference used the same monomers in the same amounts, therefore, inherently the polymer is lacking functional groups containing reactive hydrogen moieties and the adhesive is inherently non-reactive containing no post-polymerization chemical crosslinking as required by the present claims 1, 12 and 22. The Tg as claimed by claim 4 is property of the adhesive and expected to be displayed from the reference because the reference discloses polymer comprising the same monomers in amounts falling within the claimed ranges. The adhesive composition forms an adhesive layer on film, which is a backing layer, and further having a support, which reads on release liner (page 120, left column and example 1). The reference disclosed non-steroidal anti-inflammatory agents.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims**

**(MPEP §2141.012)**

Although Nakagawa exemplifies salt of the drug, however, the reference does not exclude the non-salt form of the drugs. Nakagawa does not explicitly teach fentanyl as an active agent delivered by the claimed patch to the skin as instantly claimed by claims 12 and 15-17.

Miranda teaches transdermal drug delivery device that permits selectable loading of drug into dermal formulation and adjustment of delivery rate the drug from the composition through the dermis, while maintaining acceptable shear, tack, and peel

adhesive properties (abstract). The dermal formulation comprises up to 96% polyacrylate copolymer comprises alkyl acrylate monomer copolymerized with monomer having functional groups including methacylamide (col.9, lines 21-59). Preferred drugs to be delivered by this transdermal device include fentanyl and non-steroidal anti-inflammatory drugs in non-salt form as evident by claim 1 of the reference. Miranda teaches that the active agent can be present in different forms depending on which form yields the optimum delivery characteristics. Thus, the drug can be in the form of free base or acid form, or in the form of salts, esters, or any other pharmaceutically acceptable derivatives (col.12, lines 34-39).

**Finding of Prima Facie Obviousness Rational and Motivation**  
**(MPEP §2142-2143)**

Therefore, the prior art recognized the equivalency between fentanyl and non-steroidal anti-inflammatory active agents in terms of transdermal delivery from adhesive comprising acrylate polymers comprises alkyl acrylate monomer copolymerized with monomer having functional groups including methacylamide as taught by Miranda. The art also recognized that it is within the skill of versed artisan to determine the form of the drug to be delivered, free base or acid form, or in the form of salts, esters, or any other pharmaceutically acceptable derivatives.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an acrylic adhesive polymer of (meth)acrylic acid alkyl ester and a monomer having an amide bond as taught by Nakagawa, and use the

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adhesive to deliver non-salt drugs and fentanyl as taught by Miranda. One would have been motivated to do so because Miranda recognized the equivalency between non-steroidal anti-inflammatory drugs taught by Nakagawa and fentanyl as suitable for transdermal delivery from adhesive preparation comprising alkyl(meth)acrylate monomer and functional containing monomer and because Miranda also recognized the form of the drug can be determined by the skilled artisan to obtain the optimum delivery characteristics. One would reasonably expect formulating an acrylic adhesive polymer of (meth)acrylic acid alkyl ester and monomer having an amide bond that delivers fentanyl in the non-salt form in the optimum delivery profile to the skin of a patient in need of such treatment.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa in view of Miranda as applied to claims 1, 4-7, 9-19, 21, 22 above and further in view of Akemi (EP 0531938, of record).

#### **Applicant Claims**

Applicant's claim 3 is directed to a nitrile, which nitrile is methacrylonitrile or 2-cyanoethylacrylate.

**Determination of the Scope and Content of the Prior Art**  
**(MPEP §2141.01)**

The combined teachings of Nakagawa and Miranda are previously discussed in this office action.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims**  
**(MPEP §2141.012)**

Although Nakagawa teaches monomer having an amide bond, and teaches acrylonitrile in page 119, left column, first paragraph, as suitable for inclusion in the polymer of the reference, however, the reference does not explicitly methacrylonitrile or 2-cyanoethylacrylate as instantly claimed by claim 3.

Akemi teaches medical preparation for percutaneous absorption of drugs (abstract). The preparation comprises pressure sensitive acrylic based layer obtained by polymerizing 60-98% by weight of alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and from 2-40% by weight of monomer copolymerizable with the alkyl (meth)acrylate (page 4, lines 13-19; page 26, claim 5). The monomer copolymerizable with the alkyl (meth)acrylate includes butyl acrylamide, dimethyl (meth)acrylamide, and (meth)acrylonitrile (page 4, lines 29, 36).

**Finding of Prima Facie Obviousness Rational and Motivation**  
**(MPEP §2142-2143)**

Therefore, the prior art recognized the equivalency between butyl acrylamide and dimethyl (meth)acrylamide taught by Nakagawa and (meth)acrylonitrile to polymerize with alkyl(meth)acrylate monomer.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an acrylic adhesive polymer of (meth)acrylic acid alkyl ester and a monomer having an amide bond to deliver non-salt drug or fentanyl as taught by the combination of Nakagawa and Miranda, and use (meth)acrylonitrile taught by Akemi. One would have been motivated to do so because Akemi recognized the equivalency between monomer having an amide bond taught by Nakagawa and (meth)acrylonitrile as suitable polymer to polymerize with alkyl(meth)acrylate monomer in percutaneously absorbed preparation. One would reasonably expect formulating an acrylic adhesive polymer of (meth)acrylic acid alkyl ester and (meth)acrylonitrile to deliver non-salt active agents including fentanyl effectively to the skin.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa in view of Miranda.

**Applicant Claims**

Applicant's claim 23 is directed to monomer composition of the acrylic polymer is 45 % by weight 2-ethylhexyl acrylate, 35 % by weight methyl acrylate and 20 % by weight of an N-substituted acrylamide monomer.

#### **Determination of the Scope and Content of the Prior Art**

**(MPEP §2141.01)**

The combined teachings of Nakagawa and Miranda are previously discussed in this office action.

#### **Ascertainment of the Difference Between Scope the Prior Art and the Claims**

**(MPEP §2141.012)**

Although Nakagawa teaches 2-ethylhexyl acrylate, and methyl acrylate, and teaches the combination of two (meth)acrylic acid alkyl ester monomer in the polymer composition, and further teaches the same amount of the monomers in the polymer from 1-50%, however, the reference does not explicitly teach the specific combination and amounts as instantly claimed by claim 23.

#### **Finding of Prima Facie Obviousness Rational and Motivation**

**(MPEP §2142-2143)**

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. This is the case here because all the claimed

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monomers are taught by the prior art and the claimed amounts overlaps with those taught by the prior art. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See MPEP 2144.05 [R-5].

Applicants failed to show unexpected results obtained from using the specific monomers combination in the specific amounts.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

#### ***Response to Arguments***

9. Applicant's arguments filed 04/20/2011 have been fully considered but they are not persuasive.

Applicants argue that Nakagawa fails to disclose that the therapeutic agent is a non-salt as required by amended claims 1 and 22 or fentanyl as required by amended claim 12. Nakagawa is directed to efficient percutaneous absorption of one particular active, amfenac sodium in an adhesive. Nowhere is there any suggestion that a different active or fentanyl.

This argument is moot in view of the new ground of rejection of claims 1, 4-7, 9-19, 21, and 22 over Nakagawa in view of Miranda. Nakagawa teaches "anti-inflammatory and analgesic drugs" in general, page 118, left column. Nakagawa is silent

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regarding the form of the drug. Although Nakagawa exemplifies salt of specific drug, however, the reference does not exclude other forms of the drug and the secondary reference, Miranda, suggests to one having ordinary skill in the art to use either salt or free acid or base according to the used drug. The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In any event, Miranda teaches that the active agent can be present in different forms **depending on which form yields the optimum delivery characteristics.** Thus, the drug can be in the form of free base or acid form, or in the form of salts, esters, or any other pharmaceutically acceptable derivatives. Applicants did not show unexpected results obtained from using free form of the drug over the salts thereof.

Applicants requested clarification of the statement in Office Action dated October 21, 2010 that "EP'938 recognizes the equivalency between monomer having an amide bond taught by Nakagawa and (meth)acrylonitrile as suitable polymer to polymerize with alkyl(meth)acrylate monomer".

The examiner is hereby clarifies that EP '938 teaches pressure sensitive acrylic based adhesive layer obtained by polymerizing alkyl(meth)acrylate monomer and one of butyl acrylamide, (meth)acrylamide, dimethyl (meth)acrylamide, and (meth)acrylonitrile. Nakagawa teaches pressure sensitive acrylic based layer obtained by polymerizing alkyl(meth)acrylate monomer and one of butyl acrylamide or dimethyl (meth)acrylamide. Therefore, both of butyl acrylamide and (meth)acrylonitrile were known at the time of the

invention as being suitable for copolymerization with alkyl(meth)acrylate monomer. In KSR, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art," USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. "*In United States v. Adams...* [t]he Court recognized that **when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.**" USPQ2d at 1395.

Court further stated that:

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. USPQ2d at 1396."

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devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. USPQ2d at 1396."

This applies on the present situation wherein applicants simply mirror substituted one functional monomer with another.

Applicants argue that EP '938 is directed to a reactive pressure sensitive adhesive formed using an acrylic ester-based polymer and crosslinking the polymer. Particularly, it is taught that obtaining acrylic ester-based polymers by an alkyl (meth)acrylate and at least one carboxyl group-containing monomer and hydroxyl group-containing monomer, as essential components. Thus, crosslinking the polymer is essential to EP'938. While EP '938 teaches that alkyl (meth)acrylate is copolymerized with other various monomers, the alkyl(meth)acrylate must still further react (and crosslink) with at least one carboxyl group-containing monomer and hydroxyl group-containing monomer. Unlike EP '938, the instant invention is directed to a non-reactive pressure sensitive adhesive that specifically lacks carboxyl groups and hydroxyl group containing monomers. A skilled artisan would not look to EP '938 to develop a non-reactive pressure sensitive adhesive that does not require any post-polymerization chemical crosslinking. There is no teaching, suggestion or motivation to combine the teachings of Nakagawa and EP '938.

In response to this argument, it is argued that EP '938 teaches that (meth)acrylate is copolymerized with various monomers including at least one carboxyl group-containing monomer and hydroxyl group-containing, and other various

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monomers including methacrylonitrile, as applicants themselves admit. Therefore the reference teaches copolymerization with nitrogen containing monomers as instantly claimed. Note that the claims do not exclude the presence of hydroxyl or carboxyl containing monomers. In any event EP '938 is relied upon for only simple substitution of one functional monomer by another as set forth in this office action.

Further, the reference teaches crosslinked polymer, and does not teach anywhere reactive polymer having non-crosslinked functional groups, as applicant assert. Applicants disclosed in page 5, lines 10-13, on the present specification that:

**"No post- polymerization chemical cross-linking** means that while monomers having multiple polymerization sites may be used to prepare the adhesive of the invention, following polymerization no reactive sites are present in the polymer." The reference teaches the same percentage of the monomers as instantly claimed, and this implies that all the reactive sites are reacted and no free reactive sites are present after polymerization, i.e. no crosslinker are present following polymerization. In view of applicants' definition of "no post polymerization cross linker" and the teaching of the reference, the composition of the reference lacks functional groups. In any event, EP '938 is relied upon for teaching the equivalency between butyl acrylamide, methyl acrylamide, dimethyl acrylamide and methacrylonitrile as monomer copolymerizable with alkyl methacrylate. Therefore, one having ordinary skill in the art would have been motivated to simply substitute monomer polymerizable with alkyl methacrylate with another. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are

evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

Applicants argue that *Miranda* fails to cure the defect of *Nakagawa* so as to render obvious the claimed invention. *Miranda* is directed to a blend that requires both polyacrylate and a polysiloxane. While the passage cited by the Examiner (citing *Miranda*, column 9, lines 21- 59), points to the acrylic portion of *Miranda*'s adhesive, *Miranda*, as a whole, also requires polysiloxane as a polymer component. There is no teaching, suggestion or motivation to combine *Nakagawa* and *Miranda* to arrive at the instant invention, which specifically requires fentanyl without a mutually interpenetrating polymeric network which additionally requires polysiloxane.

In response to this argument, it is argued that *Miranda* is relied upon for the teaching of forms of the drug including salt, acid, base, ester, etc., and for teaching fentanyl. The present claims' language does not exclude the presence of polysiloxane taught by *Miranda*. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide an acrylic adhesive polymer of (meth)acrylic acid alkyl ester and a monomer having an amide bond as taught by *Nakagawa*, and use the adhesive to deliver non-salt drugs and fentanyl as taught by *Miranda*. One would have been motivated to do so because *Miranda* recognized the equivalency between non-steroidal anti-inflammatory drugs taught by *Nakagawa* and fentanyl as suitable for transdermal delivery from adhesive preparation comprising alkyl(meth)acrylate monomer and functional containing monomer and because *Miranda* also recognized the

form of the drug can be determined by the skilled artisan to obtain the optimum delivery characteristics. One would reasonably expect formulating an acrylic adhesive polymer of (meth)acrylic acid alkyl ester and monomer having an amide bond that delivers fentanyl in the non-salt form in the optimum delivery profile to the skin of a patient in need of such treatment. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

It has been decided by the board that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be

made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571)272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/  
Primary Examiner, Art Unit 1611

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